



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1025]

The Science of Small Clinical Trials; Notice of Course

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA), together with the National Institutes of Health (NIH) Office of Rare Diseases Research, National Center for Advancing Translational Sciences, is announcing a course entitled “The Science of Small Clinical Trials.” The course is intended to present an overall framework and provide training in the scientific aspects of designing and analyzing clinical trials based on small study populations. The course will bring together subject experts and stakeholders to identify when such trials should be conducted, along with strategies and trial designs that are conducive to overcoming the challenges they present.

The goal of this course is to engage and educate FDA reviewers, NIH scientists, clinicians, academics and industry representatives with experience in human subject research, seeking to build upon their existing knowledge and to obtain a broader context of what is known about small clinical trials across medical products (e.g. drugs, biologics, and devices).

Date and Time: The course will be held on November 27, 2012, from 8 a.m. to 5 p.m., and November 28, 2012, from 8 a.m. to 3 p.m.

Location: The course will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Section A, Silver Spring, MD 20993-0002. Entrance for course participants (non-FDA employees) is through

Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. A live Web cast will be made available for FDA participants only. For participants who cannot attend the live course, a recorded Web cast will be made available after the course.

Contact: For information regarding this notice: Francesca Joseph, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5264, Silver Spring, MD 20993-0002, 301-796-6805, FAX: 301-847-8621, email: [Francesca.Joseph@fda.hhs.gov](mailto:Francesca.Joseph@fda.hhs.gov).

For information regarding the course and registration: Megan McNamee, ICF International, 530 Gaither Rd., suite 500, Rockville, MD 20850, 301-407-6627, email: [Megan.Mcnamee@icfi.com](mailto:Megan.Mcnamee@icfi.com).

Registration: Interested participants may register for this course at the following Web site: [https://events-support.com/events/FDA-NIH\\_Science\\_Small\\_Clinical\\_Trials](https://events-support.com/events/FDA-NIH_Science_Small_Clinical_Trials).

If you need sign language interpretation during this course, please contact Francesca Joseph at [Francesca.Joseph@fda.hhs.gov](mailto:Francesca.Joseph@fda.hhs.gov) by October 26, 2012.

The FDA-NIH Science of Small Clinical Trials Course is presented by FDA's Office of Orphan Product Development, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health; the NIH Office of Rare Disease Research, National Center for Advancing Translational Sciences; and will also include participation from outside experts in the field. This educational event will consist of live presentations provided by FDA experts from various Centers and Offices, as well as from

outside experts. It will also include case studies of regulatory trials and interactive panel discussions. The course will be recorded for subsequent posting on FDA's Web site.

(FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Dated: October 4, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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